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10/734,562	12/12/2003	Ken Michlitsch	USGINZ02512	2406
40518 7590 04/22/2009 LEVINE BAGADE HAN LLP 2483 EAST BAYSHORE ROAD, SUITE 100 PALO ALTO, CA 94303				
EXAMINER				
DÖRNBUSCH, DIANNE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,562

Applicant(s)

MICHLITSCH ET AL.

Examiner

DIANNE DORNBUSCH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 21, 25, 28, 32, 33, and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32, 35, and 36 of copending Application No. 10/734,547. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slight difference in wording does not entail a different invention.

In reference to claims 21, 25, 28, and 43, the claim limitations are found in claim 32 of copending Application No. 10/734,547

Regarding claims 32 and 33, the claimed limitations are found in claims 36 and 35 of copending Application No. 10/734,547, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 21-25, 36, 37, and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146).

Sonnenschein discloses the following claimed limitations:

Claim 21: A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy ([0001] and [0080]), the method comprising: advancing an overtube (48) within the hollow body organ in a flexible state ([0081] and Fig. 6A position a); transitioning the overtube to a rigid state to thereby substantially fix the shape of the overtube in any desired configuration ([0083]-[0084] and Fig. 6A position a'); advancing a plication device (61, 61A) through the overtube (the plication device is advance through the overtube in the manufacturing process since when the overtube is placed into the stomach it already contains the plication device); and forming a tissue fold within the hollow body organ with the plication device (Fig. 6B, 7, 10, and 11).

Claims 22 and 44: The method further comprising visualizing formation of the tissue fold ([0219]).

Claims 23 and 45: The method wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube ([0022], [0043], and [0063] where the visualization means goes from the distal end to the proximal end of the overtube through image channel (113) seen in Fig. 17).

Claims 24 and 46: The method wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube ([0022], [0043], and [0063] where the components of the visualization means have to be coupled to the distal end and the proximal end of the overtube in the channel (113)). Endoscopes contain a lens at the end of the image channel (113) which is coupled to the end so there is no fluid going into the rest of the device as well as to avoid unwanted motion of the lens.

Claims 25 and 47: The method wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease ([0062]), advancing the overtube within a hollow body organ comprises advancing the overtube through a patient's esophagus and into the patient's stomach (Fig. 6 and 10), transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the patient's gastroesophageal junction ([0083]-[0084] and Fig. 6A position a'), and forming a tissue fold comprises forming at least one tissue

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fold in a vicinity of the patient's gastroesophageal junction ([0044] and Fig. 6B, 7, 10, and 11) ([0080]-[0086]).

Claims 36 and 40: The method wherein the medical procedure comprises endoscopically treating a bleeding site within a patient's gastrointestinal tract ([0062]), advancing the overtube within a hollow body organ comprises advancing the overtube through the patient's esophagus or colon (Fig. 6 and 10), transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the bleeding site ([0083]-[0084] and Fig. 6B and 11 where the location is where a bleed is occurring or where the tumor is located), and forming a tissue fold comprises forming at least one tissue fold with a plication device advanced through, or coupled to, the overtube, so that the bleeding site is disposed on the tissue fold ([0044] and Fig. 6B, 7, 10, and 11).

Claim 37: The method further comprising removing the lesion or cancer. It is inherent that if a tumor or lesion is found in the body it will be removed.

Claim 41: The method further comprising securing the tissue fold, thereby reducing bleeding from the bleeding site (the tissue fold is secured with the staples as seen in Fig. 9B).

Claim 42: The method wherein securing the tissue fold further comprises securing the tissue fold with an anchor assembly (the staples are an anchor assembly as seen in Fig. 9B).

Claim 43: A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy ([0001] and [0080]), the method

comprising: advancing a main body (48) within the hollow body organ in a flexible state ([0081] and Fig. 6A position a), the main body having a plication device (61, 61A) coupled to a distal region thereof (Fig. 5 and [0163]); transitioning the main body to a rigid state to thereby substantially fix the shape of the overtube in any desired configuration ([0083]-[0084] and Fig. 6A position a'); and forming a tissue fold within the hollow body organ with the plication device (Fig. 6B, 7, 10, and 11).

Sonnenschein teaches all the claimed limitations discussed above however, Sonnenschein does not disclose that the overtube comprises a plurality of nested elements having mating contoured surfaces and that the rigid state is caused by imposing a load that clamps the contoured surfaces of adjacent nested elements together.

El Gazayerli discloses a method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy (Fig. 1), the method comprising: advancing an overtube (16 which is made by components 28) comprising a plurality of nested elements (28) having mating contoured surfaces (30, 32 as seen in Fig. 4C) within the hollow body organ in a flexible state (Fig. 1); transitioning the overtube to a rigid state by imposing a load that clamps the contoured surfaces of adjacent nested elements together to thereby substantially fix the shape of the overtube in any desired configuration (Col. 4 Lines 24-32).

The overtube of El Gazayerli is configured by a plurality of linkages/nested elements (28) which are connected to each other by core (34) and wires (44) which are used to move the device into predetermined shapes (Fig. 2) by causing a load

(tensioning) on the nested elements which makes the contoured surfaces clamp against each other and it locks in place in order to maintain the position to place the staples (Fig. 2 and Col. 5 Lines 28-42).

Sonnenschein discloses the claimed invention except that for the overtube being made of a flexible tube instead of a plurality of nestable elements (links). El Gazayerli shows that an overtube with links or with flexible tubing is an equivalent structure known in the art. Therefore, because these two movable joints were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the flexible tube for a plurality of nestable elements/links.

Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein with an overtube made of nestable elements in view of the teachings of El Gazayerli, in order to provide the device with the exact orientation of each contoured surfaces on the nestable elements which will ensure proper functioning of the nestable elements so the fundus is properly aligned with the staples.

5. Claims 26-35, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146) and further in view of Kalloo et al (2002/0022851).

Claims 26 and 48:

Sonnenschein discloses the method wherein the medical procedure comprises endoscopically performing gastric reduction ([0062]), advancing the overtube within a

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hollow body organ comprises advancing an overtube through a patient's esophagus and into the patient's stomach (Fig. 6 and 10), transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a desired configuration within the patient's stomach ([0083]-[0084] and Fig. 6A position a'), and forming a tissue fold ([0044] and Fig. 6B, 7, 10, and 11).

Sonnenschein discloses the claimed invention except for a plurality of tissue folds in the patient's stomach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make more than one fold in the stomach, since it would be necessary for the particular procedure to have several folds in order to reduce the size of the stomach.

Additionally, Kalloo shows as plurality of folds performed in a gastric reduction procedure (Fig. 11).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli with more than one fold in a gastric reduction procedure in view of the teachings of Kalloo, in order to securely fold more than one location to reduce the total size of the stomach.

Claims 27-30, 32-35, and 49:

Sonnenschein in view of El Gazayerli teaches all the claimed limitations discusses above, however Sonnenschein in view of El Gazayerli does not disclose the steps of partitioning the stomach with a plurality of tissue folds nor the end structure of the stomach.

Kaloo discloses the following claimed limitations:

Claim 27: The method further comprising approximating and securing the plurality of tissue folds ([0033]), thereby partitioning the patient's stomach into at least first (the pouch at the base disclosed in paragraph [0033]) and second chambers (the collapsed/closed off portion of the stomach disclosed in paragraph [0033]) over at least a portion of the stomach.

Claims 28 and 49: That forming, approximating and securing a plurality of tissue folds further comprises: forming, approximating and securing a first plurality of tissue folds in a first plane (the first plane is one side of the periphery of the stomach seen in Fig 7); and forming, approximating and securing at least one additional plurality of tissue folds in at least one additional plane (the second plane is the opposing side of the first plane in Fig. 7 where the rope is attached to the wall of the stomach in both sides in order to enclose a portion of the stomach by bringing the two planes together), wherein the first plane and the at least one additional plane are substantially parallel to one another.

Claim 29: That partitioning the stomach into first and second chambers further comprises partitioning the stomach into a first lumen (the first chamber disclosed as the pouch at the base of the esophagus has a lumen for receiving the food and digesting it ([0033])) and a second chamber (the collapsed/closed off portion of the stomach disclosed in paragraph [0033]).

Claim 30: That partitioning the stomach into a first lumen and a second chamber further comprises partitioning the stomach such that the patient's gastroesophageal

junction only communicates with the first lumen ([0033] where the pouch is at the base of the esophagus in order to receive the food and digest it).

Claim 32: That forming a plurality of tissue folds further comprises forming a plurality of tissue folds inferior to the patient's gastroesophageal junction (Fig. 7 where the clip is being placed below the esophagus junction).

Claim 33: That forming a plurality of tissue folds further comprises forming a plurality of tissue folds having at least one tissue fold from an anterior segment of the patient's stomach (the anterior segment is one side of the periphery of the stomach seen in Fig 7) and at least one tissue fold from an opposing posterior segment of the patient's stomach (the posterior segment is the opposing side of the anterior segment in Fig. 7 where the rope is attached to the wall of the stomach in both sides in order to enclose a portion of the stomach by bringing the two segments together).

Claim 34: That forming a plurality of tissue folds within a patient's stomach comprises forming and securing a plurality of tissue folds disposed at substantially randomly selected locations to reduce a volume of the stomach (Fig. 11 where there are multiple folds which are randomly placed depending at the location of the rope).

Claim 35: That forming a plurality of tissue folds within a patient's stomach comprises forming a plurality of interconnected tissue folds (Fig. 11) around a perimeter of the patient's stomach (the folds are made around a perimeter where the rope is located which is a loop in the stomach that is later closed to separate the stomach into two chambers) with instruments advanced through, or coupled to, the overtube (Fig. 7-

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11), the method further comprising approximating the plurality of interconnected tissue folds to remodel the stomach to an hourglass profile ([0033]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli with the steps of partitioning the stomach with a plurality of tissue folds and having a specific end structure of the stomach which contains two chambers in view of the teachings of Kalloo, in order to be able to securely close the stomach into two separate chambers where one acts as a smaller stomach that helps the patient loose weight.

Claim 31:

Sonnenschein in view of El Gazayerli and Kalloo discloses the claimed invention except for the first lumen having a volume in the range of 10-50 cm³. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a volume in the range of 10-50 cm³ on the first lumen, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

6. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146) and further in view of Reed (2003/0165887).

Sonnenschein in view of El Gazayerli teaches all the claimed limitations discussed above, however Sonnenschein in view of El Gazayerli does not disclose removing the lesion or cancer with cutting apparatus such as a snare.

Reed discloses removing the lesion or cancer with cutting apparatus such as a snare [0111].

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli with removing the lesion or cancer with a cutting apparatus such as a snare in view of the teachings of Reed, since the use of cutting tools such as snares are well known biopsy techniques that can be used through the port of endoscopes like the one used by Sonnenschein.

Response to Arguments

7. Applicant's arguments with respect to claims 21-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773